

PATENT OF INVENTION

For a 20 years term for an invention title

**FENESTRATED ASYMMETRIC INTRACARDIAC DEVICE FOR THE
COMPLETION OF TOTAL CAVOPULMONARY ANASTOMOSIS
THROUGH CARDIAC CATHETERIZATION**

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Fenestrated Asymmetric Intracardiac Device for the completion of total cavopulmonary anastomosis through cardiac catheterization

The aim of this Fenestrated Asymmetric Intracardiac Device is to complete the Total cavopulmonary anastomosis through cardiac catheterization.

Intended use of the Fenestrated asymmetric intracardiac device

To be used in pediatric cardiologic interventions, more specifically to correct specific congenital heart disease in hemodynamic interventions.

Former state of the art – Physiology and univentricular therapeutics

There are different congenital heart disease (CHD) with only one working ventricle available, so this disability forces to design a therapeutic strategy which allows to develop a special hemodynamic model.

These cases are present in newborns with this cardiac malformation and it is absolutely necessary to correct it by means of surgery.

During the last decades different techniques have been introduced for the sequential preparation of the circulatory system, with the final aim of connecting the venous blood that comes from the heart through the superior and inferior vena cava with the pulmonary circuit, allowing the oxygenation of blood.

This involves performing a bypass to the right ventricle, because the non-existence or rudimentary structure of this CHD does not allow to perform its force pump function towards pulmonary circulation.

The target is to maintain the blood flow through a minor circuit with the pumping function of the only active ventricle. This circuit should have a low resistance to the flow, without obstruction sites, so that blood can flow properly, even if it is not pumped with "unnatural right heart venous pathways".

The following table shows different CHDs that need surgical treatment.

Congenital heart disease with univentricular physiology

- Single ventricle
- Tricuspid atresia
- Hypoplastic left heart syndrome (HLHS)
- Pulmonary atresia with intact septum and hypoplastic right ventricle
- Transposition of the great vessels, with noncommitted ventricular septal defect and small right ventricle.
- Double outlet right ventricle and poor anatomy
- Criss cross heart
- Congenital right ventricular hypoplasia
- Ebstein's malformation

Most of these CHDs need a sequential treatment strategy. Some of them (such as hypoplastic left heart syndrome) require a special therapeutic, whose end point is common to all.

When the patient born with single ventricle (classic CHD of this pathology) and stenosis or pulmonary atresia that hinder from pulmonary flow, in order to maintain a proper oxygenation, a prompt modified **Blalock-Taussig** anastomosis should be performed with a prosthesis tube of 4 mm between the subclavian artery and the homolateral pulmonary branch, usually on the left side.

If there is not pulmonary stenosis, a banding of the pulmonary artery to narrow the lumen, to limit the flow and the pressure transmitted to the pulmonary circuit, should be performed. This prevents the development of pulmonary hypertension which would prevent the patient from advancing towards the next steps.

Under any of the two conditions described above, at the age of 6 or 8 month, patients should be subjected to a **Bidirectional Glenn** procedure. This procedure consists of the separation of the superior vena cava (SVC) from the right atrium (RA) and its connection with the right pulmonary branch. In this way all the venous flow of the superior half of the body will flow directly to the pulmonary artery (PA) to become oxygenated without coming into the heart. This is performed at this age because the head and the superior half of the body represent the 55% of the venous return. This is an open heart procedure with cardiopulmonary bypass (CB)

The last step is to complete the total cavopulmonary connection (TCPC) at the age of 3 or 4 years old, by carrying the inferior vena cava flow to the pulmonary artery under cardiopulmonary bypass (CB) too. The surgical techniques have been substantially modified in the last decades, specially in this phase. Since the early **Fontan-Kreutzer** procedure, which consisted of joining the right atrium to the right pulmonary branch (atriopulmonary anastomosis) up to the current anastomosis with extracardiac tube between SVC and PA, several techniques have been tried.

This last technique consists of the IVC anastomosis to the right pulmonary branch (RPB) with the interposition of a Gore-Tex™ extracardiac prosthesis tube with a fenestration or hole in the RA as “discharge” in order to secure the postoperative cardiac output.

At this phase, the so called “Total Cavopulmonary Connection”(TCPC) is finished. Lately, some attempts have been made by using a covered stent with a interventional catheterization to finish this last phase, and so avoid a new surgery, simplify the technique, minimize the risks as well as the side effects of EC.

These stents have an expandable tubular mesh made of different materials, such as a platinum-iridium, nickel-titanium, stainless-steel mesh and covered with an impermeable polymer, like expanded polytetrafluoroethylene (ePTFE). With these devices, after performing the **Bidirectional Glenn** procedure, IVC is connected to SVC. As well TCPC procedure with extracardiac tube as well as the procedure with the current stents have the inconvenience of supplying an unbalanced flow to the pulmonary circulation. Current stents have one or several fenestrations which allow the “discharge” of blood from the circuit, if the hemodynamic condition is not the best, allowing a right to left shunt at atrial level, so as to maintain the postoperative cardiac output. These openings or holes need to be closed or sealed when the patient hemodynamic condition allows to do so.

To show a better reference frame of the former state of the art, before this invention, figure 1 shows schematically a heart which suffers from these CHDs, before the **Glenn** procedure, and in the figure 2 this same heart after the **Glenn** procedure.

The following acronyms are used in both figures:

RPA	Right pulmonary artery
LPA	Left pulmonary artery
SVC	Superior vena cava
IVC	Inferior vena cava
SHV	Hepatic vein
Ra	Right appendage
RA	Right atrium
TV	Tricuspid valve

The following are bibliographical references of these known more recent techniques:

- **SURGICAL PRECONDITIONING AND COMPLETION OF TOTAL CAVOPULMONARY CONNECTION BY INTERVENTIONAL CARDIAC CATHETERIZATION: A NEW CONCEPT**, (Heart 1996; 75: 403-409).

Through this technique the field to complete by catheterization the total cavopulmonary connection of high risk patients is carried out during the Glenn procedure.

A left banding is done between RA and SVC, setting a Gore-Tex™ tube with 3 up to 7 perforations (multifenestrated) inside RA. During the next intervention, the banding is dilated with or without a Palmaz stent between SVC-AD, and the fenestrations are closed with Rashkind devices of 17 mm, used for the closure of the patent ductus arteriosus. If it is not possible to perform this technique, a covered stent inside a Gore-Tex™ tube is placed.

- **A NOVEL TECHNIQUE FOR ESTABLISHING TOTAL CAVOPULMONARY CONNECTION: FROM SURGICAL PRECONDITIONING TO INTERVENTION COMPLETION**, (J Thorc Cardiovasc Surg 2000; 120: 1007-9).

This technique contemplates the experimental settlement of a cavo-caval anastomosis with a covered stent through cardiac catheterization. Previously, a side to end anastomosis between SVC and distal RPB with PTFE should be performed. SVC is left banding in its joint with RA. The next procedure is to introduce, via endovascular, a stent graft from the right internal jugular vein, placing it through the SVC banding, between SVC-RPA joint and IVC over the hepatic vena end. Then the pulmonary cava-cava artery anastomosis is completed.

- **EFFECT OF BAFFLE FENESTRATION ON OUTCOME OF THE MODIFIED FONTAN OPERATION**, (Circulation 1992; 86: 1762-1769).

This technique shows the benefits of fenestration in the Fontan procedure in patients of high risk. This Study compares a group of 91 patients in which a fenestration of 4 mm has been left in the intracardiac tube with 56 patients without fenestration. It was concluded that the fenestrated tube is associated with a low mortality, less incidence of pleural effusion and less days in hospital.

Up today none of these interventions have shown optimal outcomes because in the long term a number of patients need different interventions.

From the age of 6 approximately, the percentage of systemic venous return, which is kept up to the adult age, is reached. The 35% of the pulmonary flow of a healthy adult without CHD is supplied by SVC and the 65% by IVC. The right lung, anatomically bigger, should receive approximately 55% of blood and the left lung, smaller, 45%. This implies a flow division from the IVC in 20% of the total (30.7% flow from IVC) that should run to the RPA, while the 45% left runs to the LPA.

With the CHD corrective techniques currently known, it is not always feasible to guarantee a proper division of the pulmonary blood flow, resulting in a deficient supply according to the technique used in one or the other lung, usually the left one.

Another problem of the known corrective techniques and devices of the CHDs mentioned above and which can result in serious inconveniences is the IVC transversal section in the grown up children which has an average of 18-20 mm, while the PA has an average diameter of 10-13 mm approximately. The known techniques and devices resolve this problem by connecting with a suture the superior extreme of the extracardiac conduit to the PA, and crushing it, which transforms a theoretically round

section into a theoretically elliptical transversal section, resulting in an area decrease, and so increasing the flow resistance, if the speed of blood flow is reasonably constant. The last problem is the longitudinal dimensions in case the device is intracardiac, because not all the patients anatomies have the same dimensions and so the device should be adapted to the somatic growth.

Object of this invention

The main target of this invention is to obtain a covered stent or endoprosthesis device to complete the total cavopulmonary connection or anastomosis through a cardiac catheterization procedure.

This device should be implanted in procedures performed in those CHDs which need univentricular correction. Previously, an anatomical preparation during the Bidirectional Glenn procedure should be done.

An intracardiac device is another aim of this invention, which allows a best distribution of the blood flow dynamics, being able to lead between 30 to 35% of the blood flow from the IVC to the RPA and between 65 to 70% of the blood flow to the LPA, establishing a physiological distribution of the blood flow in both lungs, which the previous Bidirectional Glenn procedure brings to the right lung.

One of the aims of this invention is a device of covered stent or endoprosthesis type which allows to stop the blood flow from the pulmonary artery trunk (in the case of banding of it) or to close the Blalock-Taussig anastomosis (in stenosis or pulmonary atresia cases).

Another aim of this invention is an intracardiac device whose transversal sections allow to compensate the shape change (flattening of the transversal section) and to obtain a reasonable constant transversal section.

The aim is an intracardiac device invention which allows adaptation and compensation of the existing dimensional differences in the RA in different patients.

The aim is the invention of a device which allows to conduct the blood from the IVC to the pulmonary artery in its join with the trunk and the pulmonary right branch.

The aim is the invention of a device which allows to discharge the blood from the fenestration towards the RA in non ideal cases ("high risk patients").

The aim is the invention of a device which allows the physiological distribution of the pulmonary flow matched with the Bidirectional Glenn procedure, improving the existing models.

The aim is the invention of a device which allows the treatment of the pulmonary tree distortion, decreasing the total resistance.

The aim is the invention of a device is to set a blood flow with the smallest powerlosses with regards to the existing one.

The aim is the invention of a device is to contemplate the heart somatic growth by its left convexity curvature and the re-expansion of its diameters.

And, the final aim is the invention of a device to derive the blood from the liver (IVC) towards both lungs, which is a physiological important circumstance which avoids the development of pulmonary arteriovenous fistulas.

Brief description of the invention

The Fenestrated Asymmetric Intracardiac Device for the completion of total cavopulmonary connection through cardiac catheterization is characterized for having a bifurcated tubular conduit, whose parts are: a first inferior portion and a second superior portion, being both portions, one after another, in accordance with the same axis which is warped in the space of the unique conduit.

The first portion is a tubular mesh covered with an impermeable polymer with a curvature of between 35° and 45°, having this first portion in its inferior end, a transversal section, substantially circular, with a diameter between 16-20 mm, while in its superior end the first portion has a transversal section, progressively flattened and with a substantially oval shape, being the transversal sections along the axis of the same area.

The lateral of this first portion presents at least a fenestration which is selectively closure and which connects the interior of this conduit with the exterior. The inferior end of this first portion can present a mesh structure without polymeric cover, defining an end of permeable conduit. This first inferior portion is followed by the second superior portion which has a tubular mesh covered, at least in some parts, by an impermeable polymeric material and with transversal sections, along the warped axis, being more oval up to get a smaller diameter of the ellipse, between 10-13 mm.

Both transversal sections are substantially of the same area after getting the second portion of this section whose diameter is smaller than 10-13 mm, it bifurcates into two branches, one of the branches being longer and the transversal sections circular with a diameter between 10-13 mm and prolonging the warped axis with a posterior inclination, while the other branch is projected after the shape of a short appendix of a transversal section substantially circular with a diameter of 10-13 mm and obliquely divergent and backwards forming with respect to the longest branch a deformed "Y"; being the length of the first portion between 60-75 mm, while the longer branch of the second portion is between 18-25 mm long, and the length of the short bifurcated axis is between 4-8 mm defining the short appendix in its bifurcation with respect to the longer longest branch with a wall portion which faces between 50%-70% of the blood flow that runs through the main tubular conduit from its inferior end. The inferior end of the first section defines a connection between the inferior vena cava and the hepatic venous, being this tubular conduit lodged inside the right atrium and anchored in the joint of this structure and the IVC, while the longest section is lodged inside the left pulmonary artery stating a relation of close contact with the internal walls and determining an obstruction of the pulmonary artery trunk, while the branch of the short length bifurcation is lodged inside the source of the right pulmonary artery.

Preferred examples to perform this invention

The following sketches together with their description will illustrate the examples of the performance of this invention.

This example of performance should be understood as one of the many possible constructions of the invention, not limiting its use, including in its protection boundary the possible equivalent means described, being the spectrum of this invention determined by the first claims attached in the Claims Chapter.

- Likewise, in this figures, the same references identify the same or equivalent means.
- Figure 1, shows schematically a heart portion with the congenital CHD, depicted above and presents only the influence area related to RA.
- Figure 2, shows the same heart portion of Figure 1 which has undergone the Glenn procedure and banding in pulmonary artery.
- Figure 3, shows a view in lateral elevation of one of the possible constructions of the invention device.
- Figure 4, shows a construction of the device in detail.
- Figure 5, shows the same device turned 90°. around its axis.
- Figure 6, shows schematically the areas relation in the transversal section with the projection of determined sections and illustrating the concept of the division of the blood flow which runs up in IVC in the device bifurcation.

- Figure 7, shows the invention device lodged inside the Figure 2 heart.
- Figure 8, shows the AA cut of Figure 3 and,
- Figure 9, shows the BB cut of Figure 3.

Figure 1 shows schematically a RA of a heart with a characteristic congenital heart disease in its previous condition, before a Glenn procedure.

Figure 2 shows the same RA after the Glenn procedure, which consists of the sectioning of SVC, suturing the superior section 1SVC to the RPA branch, joining s1, while 2SVC, which is connected to RPA is sutured and closed with s2 suture. Before a banding has been practiced in pulmonary artery.

With this intervention the heart is ready for the next interventions above depicted.

The invention contemplates an asymmetric intracardiac device which defines a covered stent or endoprosthesis form by a first inferior section (1) and a second superior section (2). Both sections (1,2) are one after the other according to the same warped axis X-X prepared in the same space forming a unique conduit.

The first inferior section (1) is a mesh, like a stent mesh, that is to say a mesh made of metallic threads joined or welded and covered with an impermeable polymeric material, such as polytetrafluoroethylene (PTFE) The inferior section (1a) of the inferior portion (1) is preferably not covered and is inserted inside the IVC, allowing the mesh portion without cover to collect the blood which comes from the VSH.

There can be two different completions with respect to the constitution of these two sections (1,2). In one of these constructions the inferior section (1) is axially inserted inside the second section (2), the joining area is shown in reference (3) and Figure 4 shows this in detail. This construction allows the Interventional Cardiologist to make a telescopic adjustment of the device total length and to adequate it to the anatomy of each patient, moving section (1b) which is inserted inside the inferior end (2a) of the superior portion (2).

The other possible completion is the one in which the inferior section (1) is followed by the superior section (2) forming only one piece.

From the material point of view, this device can be formed by a same mesh in both sections (1,2) or the inferior portion (1) can be made of a more rigid mesh, while the superior portion (2) can be made of a more flexible and soft mesh. So it is important to say that the device of the invention can present a unique mesh of equal resistance along the device, or a mesh with different rigidity and elasticity.

The first portion (1) includes a curvature between 35° - 45°, having the first section in its inferior end (1a) a transversal section substantially circular with a diameter between 16-20 mm, which is shown in figure 8, where it can be seen the AA cut of figure 3, while in its superior end this first section presents a transversal section progressively flattened and with a substantially oval shape, which is shown in figure 9 and showed by BB cut in figure 3.

One of the important characteristics of this invention in one of its preferred constructions is the transversal sections along the XX axis which have substantially the same area from the inferior end (1a) until it gets to an area (4) below the bifurcation described, precisely, having to join in this zone, when the device with the pulmonary artery joins with the RPA branch, whose average diameter is 12 mm, it must have an oval or elliptic section whose smallest diameter according to the Y axis of figure 9 is equivalent to 12 mm, which allows to rest the biggest axis of the RPA, and so manage to maintain a transversal section with the same area.

The lateral of this first section (1) presents at least a fenestration (5) of 4 mm of diameter, with selective closing, which communicates the conduit interior with the exterior of it.

After reaching this second section (2) a high equivalent to the section (4) in figure 3, this second section (2) bifurcates in two branches. One of these branches is longer and with transversal section which are substantially circular with a diameter between 10-13 mm and following the warped axis XX, indicated in reference (6), introducing it in a tight-fitting way inside the LPA, establishing an hermetic tight relation with the internal walls, and closing the pulmonary artery entrance.

The other branch (7) is projected in the shape of a short appendix of transversal sections, substantially circular, with a diameter of 10-13 mm and obliquely divergent with posterior inclination, forming with respect to the branch of major length, a distorted Y, inserting this short branch (7) into the beginning of the RPA.

In the device the first section (1) length is between 60-75 mm while the major length branch (6) of the second section is between 18-25 mm long, an the length of the short bifurcated appendix is between 4-8 mm.

Another important aspect of this invention is that it provides a distribution of the RPA and LPA flows balanced according to the physiological model.

For these the invention ponders that the branch of major length (6) should be the followed by of the warped axis XX, but from this bifurcation the transversal section (6) is substantially circular with a diameter that oscillates around 12 mm. Originated in an elliptic tubular conduct in (4) with an area equivalent to a circle with an average diameter of 18 mm, the transversal area (6) is notably smaller than the transversal section (2) in zone (4), so the short appendix (7) which is born in this area (4) is projected from the transversal area equivalent with a circumference of an average diameter of 18mm. The transition between these two transversal areas is surpassed preparing the appendix (7) of the wall (8) substantially perpendicular to the blood flow which runs through (1,2), forcing part of the flow to divert through (7) when it collides with (8).

In another words, the short appendix (7) in its bifurcation with respect to the branch of major length (6) defines a wall portion (8) which faces between 50% -70% of the projected one, which runs through the blood flow, which runs up in the tubular conduit (1,2) from the inferior end, as indicated by the arrows in figures 3 and 6. This short appendix can be covered, or can be a mesh without coating.

In another construction of the invention, is contemplated the branch (6) of the bifurcation which has a transversal section slightly decreased to its free end, with the aim of being applied in cases in which it is necessary to limit in a small average the blood volume towards LPA, and to increase the flow towards RPA, according to the Interventional Cardiologist's criterion.

Figure 5 shows the device of figure 3, projected with a lateral elevation from its left side. It is emphasized that the XX axis is warped in the space, and the end (9) of the branch (6) runs backwards like branch (7). It can also be seen, too in this figure that the transversal sections of section (2) are flattened up to gain a smaller diameter compatible with LPA diameter.

Figure 6 is an idealization which shows the area relationships between the different device branches, showing the sections which form a slight lateral perspective, as if they have straight axes and constant and circular transversal section.

This situation allows to establish that the XX axis is aligned with section (6) of the bifurcation, which is moved towards a lateral of the device, while the branch (7) of the same bifurcation is aligned with another MM axis. These two axes represent the blood flows separation and flowing through (6) and (7). In the bifurcation quoted above, it is important to stress that the portion (2) shows a transversal area (10), belonging the transversal areas (11) and (12) to sections (6) and (7). It can be seen that areas (11,12)

are smaller in magnitude than area (10), in a proportion substantially coincident with the flow rate, which derives from branches (6) or (7).

Discussion about technique application of the current invention

Figure 7 shows the device of invention placed inside RA, according to one of the several possible techniques, not being this technique neither unique nor exclusive. This technique in attaching the appendage end (Ra) with the pulmonary trunk neck with the RPA orientated towards the LPA. This attachment can be made suturing the appendage end and then making a puncture from inside the RA so that to give way to the device bifurcation (6,7) or suturing a short conduct (Con) connecting the Ra with the RPA, puncturing or cutting and passing the device section through that conduct (See figure 7).

The connection site is the joint, established before hand by surgery, between the right appendage (Ra) and the right pulmonary artery (RPA) close to the pulmonary trunk. This connection avoids the sinus node and the complication caused by conduction disorders. The surgery technique, during the previous Glenn procedure, should contemplate a reinforcement with Gore-Tex through an anastomosis of both anatomical references and attaching the surface of the superior right appendage with the inferior one of the proximal right branch. The "floor" of the right branch will open freely and the appendage "vault" will divide into cross sections with an elliptic area and then these incisions should be sutured leaving in its central section a radiopaque goost.

In its unified version, the device is auto expandable, it releases when the sheath is withdrawn, when the device is deployed from its distal end (API). It will be installed according to the anatomical features, up to bifurcation site. The deployment device arm mechanism (7) or the right branch of the bifurcation is by elastic recovery of its shape and orientation. This happens because it is perpendicularly telescoped inside the device tubular body. The primary anchorage is caused when both branches are intubated. The secondary anchorage is at IVC level.

In its version of two bodies, the distal or superior portion (2) is auto expandable and is inserted in the pulmonary branches, as depicted above. The inferior or proximal section (1) the one that have the fenestration, can be made of a more rigid material, or with a less flexible, and can be deployed with a balloon, by inserting it inside the superior portion (2).